U.S. Appln. No.: 09/674,379

REMARKS

Claim 1-15 are pending in the Application. Claims 9, 14, and 15 are withdrawn from consideration. After entry of this Amendment, claims 1-10 and 14 and 15 are canceled and claims 11-13 will be all of the claims pending in the application.

Please cancel claims 1-10 and 14 and 15.

The Abstract of the Disclosure is replaced with a new Abstract of the Disclosure to correct for spelling errors.

The Examiner indicates at page 3 of the Office Action that the first sentence of the specification does not end in a period, and therefore requires correction. However, this sentence is the title, and therefore should not require a period.

Claims 11-13 have been amended to place these claims in independent form.

Claims 11 and 12 have been amended to recite methods of treatment as opposed to pharmaceutical compositions. Such methods of treatment are supported by the specification at pages 29-31.

Claims 11-13 have been amended to recite a polypeptide "which is at least 90% homologous to the amino acid sequence shown in SEQ ID NO. 13 or 14." Support for this amendment can be found in the specification at page 6, line 2.

Claims 11-13 have been amended to include the phrase "where said fragment inhibits proliferation of smooth muscle cells." Support for the amendment may be found in the specification, for example, at page 5, lines 4-7, Examples 8 and 10, and Figures 1 and 2.

U.S. Appln. No.: 09/674,379

Claim 13 has been amended to recite an "in vitro" screening assay. Support for this

amendment may be found in the specification at page 28, first two paragraphs.

Claim 13 has been amended to include the phrase "thereby identifying compounds that

modulate the effects of said polypeptide on said cell." This amendment is supported by the

specification at page 28, lines 17-19.

Applicants assert that no new matter has been entered and respectfully request entry of

the amendment.

I. Specification

The Examiner objects to the disclosure because the first sentence of the specification

does not end in a period. Applicants assert that since this sentence is the title, no period should

be necessary.

The Examiner objects to the abstract of the disclosure because "polypetid" is misspelled.

In response, Applicants submit a new Abstract of the Disclosure correcting this, and other,

spelling errors.

II. Obviousness-Type Double Patenting

The Examiner rejects claims 1-8 and 10-13 based on provisional Obvious-Type Double

Patenting. Specifically, the Examiner asserts that claims 1-8 and 10-13 are unpatentable over

copending Application Nos. 09/083002 and 10/041016.

6

U.S. Appln. No.: 09/674,379

In response, Applicants assert that, as indicated on PAIR, Application Nos. 09/083002 and 10/041016 are abandoned, and therefore, the double patenting rejection is rendered moot.

III. 35 U.S.C. § 112, First Paragraph

(a) The Examiner rejects claims 1-8 under 35 USC § 112, first paragraph, as not complying with the enablement requirement. Specifically, the Examiner contends that the specification does not provide enablement for homologues, fragments, and homologues of fragments of the claimed cDNAs and polypeptides.

Applicants have canceled claims 1-8.

(b) The Examiner rejects claims 10-12 under 35 U.S.C. § 112, first paragraph, as not complying with the written description requirement. Specifically, the Examiner contends that the specification does not sufficiently describe *in vivo* uses of the polypeptide of SEQ. ID No: 13 and 14, and furthermore does not sufficiently describe *in vivo* uses of fragments and homologues of SEQ ID No: 13 and 14.

Applicants have canceled claim 10, and Applicants have amended claims 11 and 12 to recite an amino acid sequence as shown in SEQ ID Nos. 13 and 14, amino acid sequences at least 90% homologous to the amino acid sequence shown in SEQ ID Nos. 13 and 14, or fragments of the above that have the activity of inhibiting the proliferation smooth of muscle cells. Applicants assert that this recitation is supported by the specification since the specification defines the activity of the protein, for example, in Example 8 and 10 and Figures 1 and 2. In addition, both the human and mouse homologues inhibited proliferation of smooth muscle cells showing that

7

U.S. Appln. No.: 09/674,379

homologues of SEQ ID Nos 13 and 14 can be operable. Therefore, the claims as amended only include methods involving polypeptides sufficiently described in the specification.

Additionally, Applicants assert that the specification sufficiently describes methods of treating abnormal proliferation of smooth muscle cells using the claimed polypeptides. First, Examples 8 and 10 and Figures 1 and 2 demonstrate that the polypeptides of the invention are effective to inhibit proliferation of cultured smooth muscle cells, even after treating these cells with a mitogen (PDGF). Second, the specification at pages 29-31 describes methods of administering the composition for the treatment of disease generally. Therefore, based on this disclosure, one of skill in the art would recognize that Applicants had described methods of treating abnormal proliferation of smooth muscle cells by administering the polypeptides of the invention (the polypeptide inhibits the proliferation of smooth muscle cells in culture and Applicants describe methods of administering the polypeptide to treat such diseases). Applicants assert that claims 11 and 12 comply with the written description requirement, and accordingly, Applicants respectfully request that this rejection be withdrawn.

(c) The Examiner rejects claim 13 as not complying with the enablement requirement. Specifically, the Examiner asserts that claim 13 is not enabled for *in vivo* screening methods.

Applicants have amended claim 13 to recite *in vitro* screening methods. Applicants assert that amended claim 13 complies with the enablement requirement. Accordingly, Applicants respectfully request that this rejection be withdrawn.

U.S. Appln. No.: 09/674,379

IV. 35 U.S.C. § 112, second paragraph

(a) The Examiner has rejected claims 4 and 5 under 35 U.S.C. § 112, second paragraph.

Specifically, the Examiner asserts that the term "selectively hybridizes" is unclear.

Applicants have canceled claims 4 and 5.

(b) The Examiner has rejected claim 13 under 35 U.S.C. § 112, second paragraph.

Specifically, the Examiner contends that claim 13 omits the essential step of determining

whether a given test compound is an agonist or antagonist.

Applicants have amended claim 13 to no longer recite agonists and antagonists.

However, Applicants have amended claim 13 to include the phrase "thereby identifying

compounds that modulate the effects of said polypeptide on said cell."

Applicants assert that claim 13 as amended is not indefinite. Accordingly, Applicants

respectfully request that this rejection be withdrawn.

V. 35 U.S.C. § 102(e)

The Examiner rejects claims 1-8 and 10-13 under 35 USC § 102(e) as anticipated by US

patent 5872234 to Bandman. The Examiner contends that Bandman teaches; the polypeptides of

claims 1 and 2, the cDNA's, expression vectors, and host cells of claims 1-8, the pharmaceutical

compositions of claims 10-12, and the screening methods of claim 13.

Applicants cancel claims 1-8.

9

U.S. Appln. No.: 09/674,379

Claims 11-12 have been amended to recite methods of treating abnormal proliferation of smooth muscle cells. Applicants assert that Bandman does not disclose such methods, and therefore, claims 11 and 12 are not anticipated by Bandman.

Claim 13 has been amended to place such in independent form, and to state that the method identifies compounds that modulate the effects of the polypeptide (the effect of the polypeptide is identified in claim 13 as inhibiting the proliferation of smooth muscle cells).

Since Bandman does not show a screening assay to identify compounds that modulate the polypeptides inhibition of smooth muscle cell proliferation, Bandman cannot anticipate claim 13.

Applicants assert that claims 11-13 as amended are not anticipated by Bandman.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Amendment Under 37 C.F.R. § 1.111

U.S. Appln. No.: 09/674,379

Attorney Docket No.: Q61531

VI. Conclusion

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

Registration No. 51,793

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

WASHINGTON OFFICE 23373

CUSTOMER NUMBER

Date: December 18, 2003